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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/711,868	10/11/2004	Aldo A. Laghi	1098.61	5867
24108	7590	08/20/2008	EXAMINER	
CARLTON FIELDS, P.A. Attn: IP Dept. P.O. BOX 3239 TAMPA, FL 33601-3239				MULCAHY, PETER D
1796		ART UNIT		PAPER NUMBER
08/20/2008		MAIL DATE		DELIVERY MODE
				PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	10/711,868	LAGHI, ALDO A.	
	<b>Examiner</b>	<b>Art Unit</b>	
	Peter D. Mulcahy	1796	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on 22 April 2008.  
 2a) This action is **FINAL**.                    2b) This action is non-final.  
 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 1-30 is/are pending in the application.  
 4a) Of the above claim(s) 1-26 is/are withdrawn from consideration.  
 5) Claim(s) \_\_\_\_\_ is/are allowed.  
 6) Claim(s) 27-30 is/are rejected.  
 7) Claim(s) \_\_\_\_\_ is/are objected to.  
 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.  
 10) The drawing(s) filed on 15 October 2004 is/are: a) accepted or b) objected to by the Examiner.  
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).  
 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
 a) All    b) Some \* c) None of:  
 1. Certified copies of the priority documents have been received.  
 2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)            | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. _____ .                                    |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>1/12/05</u> .   | 6) <input type="checkbox"/> Other: _____ .                        |

## **DETAILED ACTION**

### ***Election/Restrictions***

1. Applicant's election without traverse of Group V claims 27-30 in the reply filed on 4/22/08 is acknowledged. The election of species is further acknowledged. This is somewhat moot given that there is no generically claimed additive in this grouping of claims.

### ***Drawings***

2. The drawings were received on 10/15/04. These drawings are acceptable.

### ***Specification***

3. The disclosure is objected to because of the following informalities: There is no detailed description of the drawings.

Appropriate correction is required.

### ***Claim Rejections - 35 USC § 112***

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claims 27-30 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the

invention. The “particle-filled” bladder is not enabled by the instant specification. There is no disclosure as to the type or species of the particles. Further, there is no size or hardness description of said particles. Given the lack of disclosure as to the particles, one is not sufficiently enabled so as to make and/or use the invention.

7. Claims 27-30 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

8. The recitation of “particle-filled” is indefinite. Given the lack of description of the particles one has no understanding as to the species or relative size of said particles. As such, one can not ascertain the metes and bounds of the invention and the claims are indefinite.

#### ***Claim Rejections - 35 USC § 103***

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

10. Claim 27 is rejected under 35 U.S.C. 103(a) as being unpatentable over Matula JR. et al. US 2006/0231103.

11. This patent application shows a patient interface device having a seal member. The claim language “for a respiratory mask” is an intended use, mental step, and does not further limit the claim. Figure 11 shows a nose piece having a nasal cushion comprising a bladder 126 and a chamber 128. The nasal cushion is seen to read upon

the "face-seal interface" as claimed. Paragraph [0087] describes the cushion chamber, 128, as being filled with a particulate matter, foam and/or air. The bladder is understood to be elastomeric given the flexibility and comfort properties necessary for such a cushioning device. The difference between the claimed invention and the cited art is the art teaches the use of particulate matter to fill the chamber as an option along with either foam and/or air. One of ordinary skill would find it obvious to fill the bladder with a particulate filler as claimed given the direct suggestion in the art to do so. As such the claim is obvious.

12. Claims 27-30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Barnett et al. US 2006/0076018.

13. This patent application shows a face seal interface for a respiratory mask, see 27 of figure 1. The "annular member 27" as described at [0044] is formed from a soft gel. The gel is further described at [0047] as including plasticizers and modifiers. Silicone oils are well known plasticizers and particulate fillers are well known modifiers. A covering or bladder is taught as being formed so as to enclose the gel, see [0051]. This portion further describes the bladder being formed around the gel using a vacuum. The difference between the disclosure herein and the claimed invention is the specific mention of a particle filler and silicon oil plasticizer. As stated supra, silicon oil is a well known plasticizer and the particle fillers are well known modifiers. As such, one having ordinary skill in the art would be motivated to select the particle filler and silicon oil plasticizer when the art instructs one practicing the invention to select a modifier and a plasticizer.

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14. Claims 27, 29 and 30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chen US 2003/0122446.

15. This patent document shows gels and articles formulated therefrom. The use of the gel in face mask cushioning is suggested at [0084] and [0260]. The incorporation of pigments that read on the claimed particle are discussed at [0231]. The filling of a bladder with the pigments is suggested by the disclosure at [0237] and the figures showing the gel "G" being the outer membrane or liner being filled with "M" being a material which can be a particle. The discussion at [0100] further renders obvious the use of a bladder filled with a particle. The use of silicon oil in the filled portion of the bladder is discussed at [0204]-[0212].

***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Peter D. Mulcahy whose telephone number is 571-272-1107. The examiner can normally be reached on Mon.-Fri. 8-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, David Wu can be reached on 571-272-1114. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Peter D. Mulcahy/  
Primary Examiner  
Art Unit 1796